MAR 0 5 2013

18. 510(K) SUMMARY

Applicant:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765 Phone: 800-729-9010 x8597 Fax: 909-839-8804
Contact Person:	Wayne R. Hohman Project Manager Regulatory Affairs
Date:	December 11, 2012
Trade or Proprietary Name:	PENTARAY® NAV *eco* High-Density Mapping Catheter
Common or Usual Name of Device:	Deflectable Tip Electrophysiology Catheter—Diagnostic
Classification Name:	Electrode recording catheter or electrode recording probe (21 CFR 870.1220, Product Code MTD)
Predicate Devices:	PENTARAY® NAV High-Density Mapping Catheter 510(k): K120425
Manufacturer:	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
Manufacturing Sites:	Biosense Webster, Inc 15715 Arrow Highway Irwindale, CA 91706 Cordis de Mexico, S.A., de C.V. Circuito Interior Norte 1820 Parque Industrial Salvarcar Cuidad Juarez, Chihuahua CP 32599 Mexico <u>Sterilization Sites:</u> Steris Isomedix 7685 St. Andrews Avenue San Diego, CA 92154 Sterigenics, Inc. 2400 Airport Road

Santa Teresa, NM 88008

18.1 Substantially Equivalent To

The Biosense Webster PENTARAY® NAV *eco* High-Density Mapping Catheter is substantially equivalent to the Biosense Webster PENTARAY® NAV High-Density Mapping Catheter (510(k) K120425, cleared May 24, 2013).

18.2 Description of the Device Subject to Premarket Notification

The PENTARAY® High-Density Mapping Catheter family is a 7 Fr, multi-electrode electrophysiological mapping catheter designed for diagnostic electrogram mapping and pacing in all chambers (atria and ventricles) of the heart. Six proposed PENTARAY® NAV *eco* High-Density Mapping Catheters (D-1282-07-S to D-1282-12-S) will be similar to six predicate PENTARAY® NAV High-Density Mapping Catheters (D-1282-01-S to D-1282-06-S), modified only to implement an "*eco*" Handle. The modification to implement this "*eco*" Handle involves removing the Printed Circuit Board (PCB) that is associated with the Magnetic Location Sensor from the Handle Extension and connecting this catheter to an existing "eco" Interface Cable and a short, reusable cable component that now contains this PCB. This cable containing the PCB (known as the Dongle) is associated with the CARTO® 3 Electrophysiology (EP) Navigation System. This "*eco*" Handle is the only modification of the predicate catheters to create the six proposed Biosense Webster PENTARAY NAV *eco* Catheter models.

The working tip of the six proposed PENTARAY NAV *eco* Catheters is identical to the predicate catheters. The proposed catheters will continue to have five flexible spines, each with four ring electrodes for a total of 20 electrodes. There will continue to be three different electrode spacing configurations (4-4-4, 2-6-2, or 1-8-1 mm) and two different curves (F or D) in order to accommodate different clinical situations. The tip of the shaft of both the predicate and proposed catheters house a Magnetic Location Sensor that provides magnetic location information when used with the CARTO® 3 EP Navigation System. In addition to the 20 spine electrodes, two additional Ring Electrodes are located near the tip of the shaft for a total of 22 ring electrodes that provide location information via ACL technology when used with the CARTO 3 EP Navigation System. The shafts of the proposed and predicate catheters are the same as are the distal ends of the Handle. All the modifications are in the proximal portion of the Handle where the changes described in the previous paragraph were effected.

18.3 Indications for Use

The Biosense Webster PENTARAY® NAV *eco* High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV *eco* High-Density Mapping Catheter provides location information when used with compatible CARTO® 3 EP

Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 3.x.)

18.4 Performance Data

The PENTARAY® NAV *eco* High-Density Mapping Catheter underwent Bench Testing and passed all intended criteria in accordance with appropriate standards and test criteria. The only animal test that was conducted was one to confirm that the proposed device had not change in the quality of the ECG signals. No clinical testing was deemed necessary.

18.5 Overall Performance Conclusions

The nonclinical studies demonstrate that the PENTARAY® NAV *eco* High-Density Mapping Catheter is safe and effective for anatomic mapping of the heart and establish equivalence of the PENTARAY® NAV *eco* High-Density Mapping Catheters to their predicate devices, the PENTARAY® NAV High-Density Mapping Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Biosense Webster, Inc
Wayne Hohman,
Project Manager, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K123837
Trade/Device Name: PENTARAY® NAV *eco* High-Density Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe
Regulatory Class: Class II
Product Code: MTD
Dated: December 11, 2012
Received: February 4, 2013

Dear Mr. Wayne Hohman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

7. INDICATIONS FOR USE STATEMENT

510(k) No (if known):

Device Name: PENTARAY® NAV *eco* High-Density Mapping Catheter

Indication for Use:

The Biosense Webster PENTARAY® NAV *eco* High-Density Mapping Catheter is indicated for multiple electrode electrophysiological mapping of cardiac structures in the heart, i.e., recording or stimulation only. This catheter is intended to obtain electrograms in the atrial and ventricular regions of the heart. The PENTARAY® NAV *eco* High-Density Mapping Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 3.x.)

Prescription Use ____√____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S